

# **SUBCOMMITTEE NO. 3**

## **Agenda**

### **Health, Human Services, Labor & Veteran's Affairs**

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**Chair, Senator Elaine K. Alquist**

**Senator Alex Padilla**  
**Senator Dave Cogdill**



**March 5, 2006**

**1:30 PM**

**Room 4203**  
**(John L. Burton Hearing Room)**

(Consultant: Diane Van Maren)

<b><u>Item</u></b>	<b><u>Department</u></b>
<b>4265</b>	<b>Department of Public Health (<i>Selected Issues as Noted</i>)</b>

**PLEASE NOTE:** Only those items contained in this agenda will be discussed at this hearing. *Please* see the Senate File for dates and times of subsequent hearings.

Issues will be discussed in the order as noted in the Agenda unless otherwise directed by the Chair. Thank you.

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## **Department of Public Health**

### **A. OVERALL BACKGROUND**

**Purpose and Description of New Department of Public Health (DPH).** Effective *July 1, 2007*, pursuant to Senate Bill 162 (Ortiz), Statutes of 2006, specific programs and public health responsibilities currently vested with the Department of Health Services will transfer to the newly established Department of Public Health (DPH).

The creation of a separate DPH is intended to elevate the visibility and importance of public health issues. It is also intended to result in increased accountability and improvements in the effectiveness of DPH programs the Department of Health Care Services programs by allowing each department to administer a narrower range of activities and focus on their respective core missions

Other medical treatment service programs, such as the Medi-Cal Program, California Children's Services Program and others, will remain with the existing Department of Health Services. The Department of Health Services will be renamed to be the Department of Health Care Services.

**A thoughtful and deliberate transition from the current structure to the new reorganization configuration is crucial to the success of the reorganization.** A poorly executed reorganization could potentially handicap the new departments unnecessarily.

**The legislation requires that the reorganization from one department to two departments be budget neutral, resulting in no increases to the General Fund or other state funds, including special funds.** Further, no new positions can be added to either department solely for the purpose of reorganization.

**The new DPH will administer a broad range of public and environmental health programs. The mission of the DPH is to protect and improve the health of Californians primarily through population-based programs, including the:** (1) prevention and control of chronic diseases; (2) investigation, prevention and control of infectious disease; (3) prevention and control of environmental and occupational diseases; (4) regulation of public drinking water; (5) regulation of medical waste handling and disposal; (6) regulation of food safety; (7) regulation of medical device approval; (8) regulation of low level radioactive waste disposal; and (9) coordination of family-centered preventive and primary care services to low-income women, infants, children and families. In addition, the DPH disburses and monitors funds allocated to counties for emergency preparedness functions and for certain health related services.

**Core Functions of New Department.** The core functions of the new DPH will include: (1) Emergency Preparedness; (2) Communicable Disease Control; (3) Chronic Disease and Injury Prevention; (4) Laboratory Sciences; (5) Family Health Programs; (6) Environmental and Occupational Health; (7) Drinking Water and Environmental Management; (8) Food,

Drug and Radiation Safety; **(9)** Health Statistics; **(10)** Health Facility Licensure and Certification; **(11)** Office of Multicultural Health; and **(12)** Office of Binational Border Health.

**Overall Governor's Budget for the Department of Public Health (DPH).** The budget proposes expenditures of \$3 billion (\$394.2 million General Fund) for the DPH. Of this total amount, \$716 million (\$116.5 million General Fund) is for state support and is used to fund 3,284 positions. The remaining \$2.3 billion (\$278 million General Fund) is for local assistance.

<b>Summary of Expenditures for Department of Public Health</b> (dollars in thousands)	<b>2007-08</b>
<b>Public Health Emergency Preparedness</b>	<b>\$149,699</b>
<b>Public and Environmental Health</b>	<b>\$2,649,758</b>
Chronic Disease Prevention and Health Promotion	\$290,341
Infectious Disease	\$536,170
Family Health	\$1,489,654
Health Information and Strategic Planning	\$32,377
County Health Services	\$70,413
Environmental Health	\$230,803
<b>Licensing and Certification Program</b>	<b>\$210,766</b>
Licensing and Certification of Facilities	\$202,673
Laboratory Field Services	\$8,093
<b>Total Expenditures for Department of Public Health</b>	<b>\$3,010,223</b>
<b>Funding Sources</b>	
General Fund	\$394,172
Federal Funds	\$1,468,510
Genetic Disease Testing Fund	\$118,856
Licensing and Certification Fund	\$77,895
WIC Manufacturer Rebate Fund	\$297,401
AIDS Drug Assistance Program Rebate Fund	\$91,890
Water Security, Clean Drinking Water, Beach Protection Fund	\$111,233
Safe Drinking Water Account	\$11,278
Drinking Water Treatment and Research Fund	\$5,054
Childhood Lead Poisoning Prevention Fund	\$20,810
Birth Defects Monitoring Fund	\$4,174
Radiation Control Fund	\$22,470
Food Safety Fund	\$6,328
Reimbursements	\$141,666
Other Special Funds	\$238,486
<b>Total Expenditures</b>	<b>\$3,010,223</b>

## **B. ISSUES FOR “VOTE ONLY” (Items 1 to 8—through to Page 12)**

### **1. Women, Infant & Children Supplemental Food (WIC)—State Staff Request**

**Issue:** The department requests authority to **(1) establish two positions (two-year limited-term), and (2) extend two existing positions for two-years** for the WIC Program to comply with requirements of the federal Child Nutrition and WIC Reauthorization Act of 2004. The four requested positions include an Associate Information Systems Analyst, a Staff Information Systems Analyst, and two Associate Governmental Program Analysts.

**The positions are to be funded using federal funds redirected from administrative operating expenditures (from general expenses) from within the program. The total amount to be *redirected* for these positions is \$401,000 (federal funds).**

**The department states these positions are required to comply with provisions of the federal Child Nutrition and WIC Reauthorization Act of 2004.** This Act establishes new requirements for state WIC agencies to ensure that the WIC Program pays all vendors competitive prices for supplemental foods. Among other things, these requirements affect how WIC identifies, authorizes and reimburses its 3,700 retail food vendors. **Failure to implement the federal changes could result in fiscal penalties of up to \$48 million annually.**

**Key functions to be performed by these positions include the following:**

- **Conduct expanded WIC vendor management activities, including: (1)** revising program policies to meet new federal requirements; **(2)** establishing and conducting federally required reviews of vendors; **(3)** implementing and maintaining a vendor peer group system, and competitive price criteria and reimbursement levels by peer group as required; **(4)** revising state regulations for vendor management; and **(5)** ensuring that federal reporting requirements are completed as required.
- **Modify WIC’s existing “Integrated Statewide Information System” (ISIS) to accommodate the new federal requirements,** including: **(1)** modifying the food voucher redemption system; **(2)** improving the functionality of the issuance of WIC checks to retail vendors; **(3)** designing and maintaining reports for assessing the impact of cost containment efforts as required; and **(4)** designing and maintaining various evaluation and audit reports.

The department states that the information systems changes to ISIS pertain to the functionality included in the original Feasibility Study Report (FSR) for ISIS and can be incorporated in on-going maintenance. As such, they state no new special project report is required.

**Background—What is WIC?** WIC is a federally funded program for low-income women who are pregnant or breastfeeding and for children under age five who are at nutritional risk. WIC’s objective is to provide nutritious foods, nutrition education, breastfeeding promotion and education, and referrals to health and social services programs.

In California, about 1.4 million WIC participants receive food checks each month. WIC offers over 200 different types of food checks, including checks for milk, eggs, cheese, cereal, and infant formula, that vary based on the needs of the individual participants. There are presently over 3,700 WIC authorized grocery stores.

For 2007-08, California's WIC Program is anticipated to expend a total of about \$1.175 billion (total funds, including federal grant funds and manufacturer rebate funds), contingent upon the state's final federal grant level, and manufacturer's rebate level (i.e., for baby formula, juice and cereal).

**Background—Child Nutrition and WIC Reauthorization Act of 2004:** This Act established new requirements for state WIC agencies to ensure that the WIC Program pays all vendors competitive prices for supplemental foods.

To comply with this Act, states were expected by October 1, 2006, to authorize only those vendors with competitive prices, establish separate reimbursement criteria for groups of vendors who have similar prices (peer groups), and identify those vendors who primarily serve WIC participants and set reimbursement levels for them to ensure that they are cost neutral to the program. California met this deadline.

In addition, this Act also requires states to: (1) develop a list of authorized suppliers of infant formula and require that WIC grocers purchase only from suppliers on this list; (2) collect and evaluate vendor shelf prices routinely to ensure on-going competitive pricing; (3) issue food checks that participants can redeem at any WIC vendor; (4) implement changes to the WIC food package that will offer food items to better reflect current nutritional standards; and (5) demonstrate that their systems have certain audit controls in place and that their WIC Program is operating efficiently.

**Subcommittee Staff Recommendation:** The budget request for the four limited-term positions as specified seems reasonable based on the workload requirements. The redirection of \$338,000 (federal funds) from administrative support ensures that funds are not being taken away from providing WIC food checks to women and children for this purpose. As such, no issues have been raised. **It is recommended to approve as budgeted.**

(Vote Only Calendar continued)

**2. Women, Infant & Children Supplemental Food (WIC)—State Staff Request**

**Issue:** The WIC Program is requesting to **(1) establish two new permanent positions, and (2) extend three existing limited-term positions (extend until December 2008) to expand the Breastfeeding Peer Counseling Program within WIC.**

The two new permanent positions include a Nurse Consultant II and an Associate Governmental Program Analyst (AGPA). The three positions to be extended include two Public Health Nurse Consultant II's and a Health Program Specialist I. **The positions will be used to expand WIC's Breastfeeding Peer Counseling Program to all 82 WIC agencies and to more efficiently utilize WIC food expenditures.**

**The positions are to be funded using federal funds redirected from administrative operating expenditures (from general expenses) from within the WIC Program. The total amount to be *redirected* for these positions is \$493,000 (federal funds).**

The department states that planning the expansion to all WIC agencies will require considerable state support. It will require travel to all 82 WIC agencies to conduct site visits, develop and monitor corrective action plans, and provide telephone follow for technical support. **State staff will also provide (1) training to programs in the community that provide home visiting services for WIC clients (such as the Black Infant Health Program), (2) assistance with the development of county-specific strategies, (3) training on program operation efficiencies, and (4) outreach assistance to local neighborhood and community-based organizations.**

**Background—WIC's Breastfeeding Peer Counseling Program.** The federal Department of Agriculture provides an annual grant of \$2.15 million (federal funds) to California for this program which is used to develop and operate breastfeeding peer counseling programs serving 37,500 pregnant and breastfeeding WIC participants. While operation for only three years, California WIC agencies have succeeded in increasing the percentage of infants fed exclusively with breast milk. However, more work needs to be done as illustrated by the following statistics:

- Only 54 percent of the mothers participating in the WIC Program initiate breastfeeding as compared to 75 percent of all California mothers; and
- Only 21 percent of mothers participating in the WIC Program are breastfeeding their infants at six months of age as compared to 42 percent of all California mothers.

The costs savings of breastfeeding include reductions in illness in infants and their associated medical visits and time lost from work by parents. There is also evidence that lack of extended breastfeeding contributes to overweight and obesity later in life. According to WIC, California could avoid \$476 million a year in health care costs and lost wages if just 50 percent of mothers breastfed exclusively for six months.

**Subcommittee Staff Recommendation:** The budget request for these positions is reasonable based on the workload requirements. The redirection of administrative expenditures for this purpose is also reasonable. **It is recommended to approve as budgeted.**

(Vote Only Calendar continued)

**3. Senate Bill 1759 (Ashburn), Statutes of 2006—Environmental Health**

**Issue:** The budget proposes an increase of \$99,000 (Registered Environmental Health Specialist Fund) to fund an Associate Governmental Program Analyst (AGPA) position to establish a continuing education program for Environmental Health Specialists as enacted in SB 1759 (Ashburn), Statutes of 2006.

This legislation increased the fees paid by Environmental Health Specialists in order to fund this new education program. This proposal has no affect on the General Fund

The AGPA position would implement and administer the continuing education program as contained in the enabling legislation. Specifically, they will identify the core competencies with within the profession that must be maintained through continuing education and will assess courses to determine if they meet specific content requirements to make them eligible for continuing education units.

**Background:** The Registered Environmental Health Program works to protect the public's health by solving complex environmental health issues and enforcing statutes, codes and local ordinances relevant to environmental health requirements. This includes environmental issues related to food safety, medical waste disposal, waterborne diseases, recreational health, air quality, solid waste disposal, water quality, housing, and emergency preparedness. The program is fully supported by fee revenues.

**Subcommittee Staff Recommendation:** The budget request is consistent with the legislation. **It is recommended to approve as budgeted.**

(Vote Only Calendar continued)

**4. Sexual Violence Victim Services Fund Pass Through**

**Issue:** The budget proposes an increase of \$174,000 (CA Sexual Violence Victim Services Fund) within the Department of Public Health (DPH) in order to comply with Assembly Bill 190, Statutes of 2005. These funds are directly provided to the California Coalition Against Sexual Assault (CALCASA) to provide grants to support their rape crisis center programs for victims of rape and sexual assault.

**Background:** Voluntary contributions through the tax check-off portion of personal income tax forms are deposited into the Sexual Violence Victim Services Fund. AB 190, Statutes of 2005 require funds to be allocated first to the Franchise Tax Board and State Controllers office for their collection of the revenues and administration of revenues, and then to the DPH for disbursement of the funds to CALCASA. In order to allocate the funds, the DPH must have appropriation authority.

The CALCASA would utilize the \$174,000 (CA Sexual Violence Victim Services Fund) to provide grants to California's 84 rape crisis centers to support their work with victims of sexual violence.

**Subcommittee Staff Recommendation:** The budget request is consistent with the legislation. No issues have been raised. It is **recommended to approve as budgeted.**

(Vote Only Calendar continued)

**5. Prostate Cancer Treatment Program (IMPACT Program)**

**Issue:** The budget proposes to appropriate \$3.478 million (General Fund) to maintain a prostate cancer treatment program primarily implemented through a contract with the University of CA at Los Angeles (UCLA). The Administration also states their intent to fund this program at the same level in 2008-09.

**The proposed budget amount is the same level of funding provided in 2006-07. It should be noted that enrollment into the program is based on budget availability (i.e., this is not an entitlement program).**

The IMPACT Program has been implemented through a contract with UCLA since its inception in 2001. Effective June 1, 2006, a new three-year contract was awarded through a competitive process. According to the department, the contract has been fully updated to account for changes contained in Senate Bill 650 (Ortiz), Statutes of 2006.

Senate Bill 650 (Ortiz), Statutes of 2005, re-established the IMPACT Program and required that 87 percent of any state appropriation for the program be expended on direct medical care with the remaining amount to be spent on various administration. Additionally, the program must now use Medi-Cal rates for treatment services.

**Background—Improving Access, Counseling and Treatment for Californians**

**(IMPACT) Program:** This program was designed to be a comprehensive delivery model including treatment costs as well as nutrition counseling, transportation, extensive nurse case management, essential medical supplies, and culturally appropriate patient education materials. Enrolled men are assigned case managers who coordinate care, provide emotional support, educate and counsel men on symptom management and nutrition.

Eligible low-income, uninsured men with prostate cancer who are enrolled in this treatment program will receive treatment services. UCLA estimates that from 400 men up to 800 men are anticipated to be enrolled in the current year.

**Subcommittee Staff Recommendation:** The budget request is consistent with the legislation. No issues have been raised. It is **recommended to approve as budgeted.**

(Vote Only Calendar continued)

**6. Trailer Bill Legislation—County Medical Services Program**

**Issue:** The Administration is proposing trailer bill legislation to extend for one-year the state's obligation to provide \$20.2 million (General Fund) to the County Medical Services Program (CMSP) stream of funding.

Since the enactment of Realignment in 1991, the state has been statutorily obligated to provide up to \$20.2 million (General Fund) to meet some of the expenditures of the program. **However commencing in 1999, annual trailer bill language has been enacted to exempt the state from this General Fund appropriation.**

It should be noted that in prior years (since 1999), the CMSP has been operating an efficient and effective health care program for medically indigent adults who are not eligible for the Medi-Cal Program, as specified below, without the appropriation of this \$20.2 million (General Fund) amount.

**Background—What is the County Medical Services Program (CMSP)?** Created in 1983, the CMSP is a county-operated provider reimbursement program serving medically indigent adults who are not eligible for Medi-Cal and reside in one of California's 34 small, rural counties. **CMSP is funded using monies derived primarily from County Realignment Funds and county general purpose revenues. It is administered by a CMSP Board and appointed staff.**

Since the enactment of Realignment in 1991, the state has been statutorily obligated to provide up to \$20.2 million (General Fund) to meet some of the expenditures of the program. However commencing in 1999, yearly trailer bill language has been enacted to exempt the state from this General Fund appropriation.

**Subcommittee Staff Recommendation—Suspend for One-Year:** Subcommittee staff recommends approval of the Administration's trailer bill language to defer the \$20.2 million (General Fund) amount **for 2007-08.**

(Vote Only Calendar continued)

**7. Senate Bill 144 (Runner), Statutes of 2006—CA Retail Food Code**

**Issue:** The budget proposes an increase of \$20,000 (Retail Food Safety & Defense Fund) for expenses and equipment to support the implementation of SB 144 (Runner), Statutes of 2006.

Among other things, this legislation requires the department to respond to industry requests for specified services, including the review of food safety plans and the issuance of variances to allow new technology or new scientifically validated food handling procedures to be approved in California.

**The department assumes they will receive about 25 to 30 industry requests for these reviews each year.** The department is reimbursed through the Retail Food Safety & Defense Fund, established by the legislation, for each request.

It should be noted that local environmental health agencies are assigned primary enforcement responsibility for most of the provisions contained in SB 144, Statutes of 2006.

**Subcommittee Staff Recommendation:** The request is consistent with the legislation and no issues have been raised. **It is recommended to approve as requested.**

(Vote Only Calendar continued)

**8. Botulism Prevention—Low Acid Canned Food Canneries**

**Issue:** The budget requests an increase of \$326,000 (Cannery Inspection Fund) to fund three positions—two Senior Food and Drug Investigators and a Management Services Technician—to inspect low acid canned food canneries. The purpose of these inspections is to ensure that the food products produced at these canneries are without botulism toxin contamination.

The Administration is requesting these positions to address an increase in the number of canneries to be inspected. Specifically, the department states that ten new canneries began operations in California in 2005 and three other canneries have recently expanded their operations. Further, the department states that an additional 7 cannery license applications are underway. **The requested positions are based upon the anticipated workload that is commensurate with the level of anticipated cannery production.**

Existing law requires the food industry to fully fund the department for their inspection services through reimbursement to the Cannery Inspection Fund.

Currently there are nine Senior Food and Drug Investigators to conduct inspection and oversight duties at 165 licensed canners who produce 120 million cases of canned goods each year. The amount of service provided to each canner is commensurate with the level of production the canner engages in, and the amount of cases produced.

**Background—CA Cannery Inspection Program:** The department's Food and Drug Branch licenses and inspects about 165 canneries. The foods inspected under this program are shelf-stable soups, vegetables, meat products, fish salsas, sauces and various beverages that are packed in cans, jars, and aseptic packages. Inadequate sterilization or acidification of low acid canned foods combined with anaerobic conditions in the container can lead to botulism toxin production.

The department conducts inspections of the facilities and reviews production records to ensure that all products have met official sterilization requirements or acidification requirements before the firm is allowed to release their products into commerce.

All new applicants for cannery licensure must undergo a thorough inspection of their facilities, records, operations, and personnel prior to being issued a license. The firms are scheduled for full inspections on an annual basis. These annual inspections provide a more comprehensive review of firm operations than the daily sanitation inspections conducted while staff are at the facility performing product review and release work.

Existing law requires the food industry to fully fund the department for their inspection services through reimbursement to the Cannery Inspection Fund.

**Subcommittee Staff Recommendation:** The request is consistent with the anticipated workload as described by the department and no issues have been raised. **It is recommended to approve as requested.**

## C. ISSUES FOR DISCUSSION

### **1. Organization of the New Department of Public Health (See Chart in Handouts)**

**Issue:** The budget proposes to **(1)** establish a new Department of Public Health (DPH), **(2)** transfer \$3.010 billion (total funds) to the DPH, and **(3)** reorganize and shift programmatic expenditures across a *wide variety* of programs.

**As required by the enabling legislation, the creation of the DPH must be budget neutral (which does not mean cost neutral).**

This is an important and complex issue. A thoughtful and deliberate transition from the current structure to the new reorganization configuration is crucial to the success of the reorganization. A poorly executed reorganization could potentially handicap the new departments unnecessarily.

Senate Bill 162 (Ortiz), Statutes of 2006, establishes a new Department of Public Health (DPH) and statutorily transfers specified responsibilities from the Department of Health Services effective July 1, 2007. The creation of a separate DPH is intended to elevate the visibility and importance of public health issues. It is also intended to result in increased accountability and improvements in the effectiveness of DPH programs.

**There are *four key areas* to review with respect to this reorganization and its implications. These include the following:**

- (1)** The proposed organizational structure of the new DPH—both the newly proposed “programmatic centers”, as well as all Administrative functions;
- (2)** Clarification of positions to be established and reclassified as a part of the new proposed structure for the DPH;
- (3)** The costs associated with the reorganization that must be absorbed; and
- (4)** The need for overall transparency in the establishment of the new DPH.

Each of these components is discussed separately below.

**Proposed Organizational Structure for the New Department of Public Health (See Chart in Handouts):** There are two key components to the proposed organizational structure of the new department—**(1)** creation of new “programmatic centers” and **(2)** development of a traditional administrative structure, for example a Director’s Office, personnel, and fiscal, that does not now presently exist.

As part of the creation of the new department, the Administration has reorganized its structure into **five “programmatic centers”**, each of which emphasizes a distinct aspect of public health. These include: **(1)** preventing chronic disease, injury, and environmental and occupational exposures; **(2)** combating infectious diseases; **(3)** promoting family health; **(4)** regulating the environment; and **(5)** providing quality services through licensed providers.

The figure below displays this proposed five “programmatic center” structure, as does the chart in the Handout packet. **The Administration would use a total of 25 staff positions to create these new centers.** Existing staff from within the programs must be redirected **for these efforts. This programmatic center structure was *not* part of the enabling legislation.** The Administration contends that this proposed structure actually flattens the organization overall and will lead to more direct accountabilities.

**The 25 positions for the programmatic centers are coming from the following areas:**

- Eleven positions from the existing Prevention Services section of the Department of Health Services (DHS);
- Seven positions have not yet been identified (from where to be redirected);
- Three positions exist within the Primary Care & Family Health Office and are to be used for the Center for Family Health, with an additional position being redirected; and
- Three positions exist within the Licensing and Certification area and will be used for the Center for Healthcare Quality.

<b>Department of Public Health Proposed Programmatic Organization (“Centers”)</b>	<b>Positions Added for Each Center</b>
<b>1. Center for Chronic Disease Prevention &amp; Health Promotion</b> <ul style="list-style-type: none"> <li>• Chronic Disease &amp; Injury Control</li> <li>• Environmental &amp; Occupational Disease Control</li> </ul>	<b>6 Total Positions</b> Deputy Director Assistant Deputy Staff Services Manager Associate Analyst Support Staff (2)
<b>2. Center for Infectious Disease</b> <ul style="list-style-type: none"> <li>• Office of AIDS</li> <li>• Communication Disease Control</li> </ul>	<b>6 Total Positions</b> Deputy Director Assistant Deputy Staff Services Manager Associate Analyst Support Staff (2)
<b>3. Center for Family Health</b> <ul style="list-style-type: none"> <li>• Women, Infant &amp; Children Supplemental Food</li> <li>• Maternal, Child, and Adolescent Health</li> <li>• Genetic Disease</li> </ul>	<b>4 Total Positions</b> Deputy Director Assistant Deputy Staff Services Manager Support Staff
<b>4. Center for Environmental Health</b> <ul style="list-style-type: none"> <li>• Food, Drug &amp; Radiation Safety</li> <li>• Drinking Water &amp; Environmental Management</li> </ul>	<b>6 Total Positions</b> Deputy Director Assistant Deputy Staff Services Manager Associate Analyst Support Staff (2)
<b>5. Center for Healthcare Quality</b> <ul style="list-style-type: none"> <li>• Licensing &amp; Certification</li> <li>• Laboratory Field Services</li> </ul>	<b>3 Total Positions</b> Deputy Director Assistant Deputy Support Staff
<b>Total Positions for the Centers</b>	<b>25 Positions</b>

In addition to the above programmatic centers, the new DPH needs to establish an administrative structure, including an Office of the Director, Information Technology Services, Office of Legal Services, Internal Audits, Personnel Administration, Office of Civil Rights, Fiscal Management, and other related administrative functions.

**In order to establish the administrative structure, a total of 57 positions (11 positions within the existing administrative structure are to be reclassified) are to be used.** In addition, 21 of the 57 identified positions are vacant.

The chart below provides a summary of the positions to be reconfigured.

<b>Department of Public Health: Summary of Positions for Restructuring</b>	<b>Positions</b>
1. New Programmatic Centers	25 Positions
2. Administrative Structure for New Dept.	57 Positions
<b>Total Positions to be Reconfigured</b>	<b>82 Positions</b>

**Costs Associated with Reorganization that Must Be Absorbed:** The legislation requires that the reorganization from one department to two departments be *budget neutral*, resulting in no increases to the General Fund or other state funds. **However, the split of the department is not cost neutral.**

**Chart: Costs to Be Absorbed Within Existing Budgets**

<b>Category and Type of Expense</b>	<b>Total Costs</b>	<b>General Fund</b>	<b>Federal Funds</b>	<b>Other Funds</b>
<b>One-Time Costs for 2006-07</b>				
Construction Costs	\$800,000	\$264,000	\$339,000	\$197,000
Equipment	\$100,000	\$33,000	\$42,000	\$25,000
Change & Transition Mgmt Office	\$100,000	\$33,000	\$42,000	\$25,000
Organizational/Leadership Contract	\$180,000	\$59,000	\$59,000	\$62,000
<b>TOTAL One-Time for 2006-07</b>	<b>\$1,180,000</b>	<b>\$389,000</b>	<b>\$482,000</b>	<b>\$309,000</b>
<b>Estimated Expenditures for 2007-08</b>				
One-Time Costs				
Moving 200 staff at \$500 per person	\$100,000	\$33,000	\$42,000	\$25,000
On-Going Expenditures				
Information Technology (3 yrs)	\$500,000	\$139,000	\$238,000	\$123,000
Net Cost of Positions (includes redirected and reclassified)	\$1,410,000	-\$691,000	\$904,000	\$1,197,000
Distributed Administration Change	0	\$583,000	\$875,000	-\$1,458,000
<b>TOTAL Expenditures for 2007-08</b>	<b>\$2,010,000</b>	<b>\$64,000</b>	<b>\$2,059,000</b>	<b>-\$113,000</b>
<b>TOTAL Expenditures-Both Years</b>	<b>\$3,190,000</b>	<b>\$453,000</b>	<b>\$2,541,000</b>	<b>\$196,000</b>

Costs associated with the reorganization are being absorbed within existing budgets (both the DPH as well as the revamped Department of Health Care Services). The Administration says it is their intent to have expenditures from the split absorbed equally by the two departments. **At this time, it is anticipated that about \$3.1 million (total funds) in costs are associated with the reorganization and must be absorbed over the course of the current-year and budget-year.**

**The department has not yet articulated the programmatic affects of absorbing these costs. Hopefully this requested information will be provided soon.**

**The proposed expenditures in the current-year include the costs for two consultant contracts.** These include a contract for “change management and support services” and a contract for “organizational leadership development”.

Hubbert Systems Consulting will be providing an analysis with recommendations regarding **(1)** developing and tracking transition plans for the reorganization; **(2)** proving an organizational impact report, including action plans to address the needs of employees or entities most impacted by the reorganization; and **(3)** providing ongoing oversight on the execution of the reorganization project.

The Center for Health Leadership and Practice at the Public Health Institute will be providing various products regarding organizational leadership development. This work primarily involves **(1)** the preparation of a departmental assessment report providing key information about strengths, weaknesses, opportunities and threats, and **(2)** developing a leadership development plan.

**Legislative Analyst’s Office Comment—Need for More Transparency:** The LAO believes that the proposed flattening out of the organization into programmatic centers that report directly to the Chief Deputy Director of Policy and Programs (as shown on the chart) has the potential to expedite policy and budget decisions at the DPH. Additionally, they believe that the separation of chronic disease, infectious disease, and environmental health into discrete centers would allow these program areas to be more specialized.

**However, the LAO has considerable concern with the need for increased transparency in the public health program area regarding its administrative and budgeting functions.** In past years, the Administration provided supplemental schedules that gave detailed information about local assistance expenditures and appropriations, as well as federal funds. Without this information, as well as other detailed fiscal charts, it is difficult to complete a thorough analysis of the Administration’s proposal in this area.

**Therefore, the LAO recommends (1)** holding this issue “open” pending receipt of further fiscal information, and **(2)** to adopt reporting language for the Administration to provide expanded fiscal information in future budget documents.

**Subcommittee Staff Recommendation—Hold “Open” Needs More Detail:**

Subcommittee staff also recommends holding this issue “open” pending receipt of additional information and the crafting of fiscal accountability language, as well as other reporting language in order to monitor the progress of this critical restructuring. **More comprehensive information needs to be provided regarding (1)** the staffing compliment of the new department, **(2)** the supposed benefit to creating the proposed “programmatic centers”, **(3)** the potential affect of the absorbed expenditures and redirection of staff on existing programs, and **(4)** some of the products to be obtained from the two contractor’s.

Subcommittee staff will be working with the LAO, Administration and others to craft both fiscal accountability language as well as reporting language to monitor the progress of the restructuring.

**Questions:** The Subcommittee has requested the Administration to respond to the following questions.

1. Please provide a brief summary of the reorganization to develop the new Department of Public Health.
2. Using the chart shown above, please describe the purpose of the new programmatic centers and how they are going to be staffed.
3. Using the chart shown above, please describe the costs—both current year and budget year—associated with the restructuring. Specifically, how are these costs to be absorbed?
4. Please briefly describe the key products to be produced by the two contractors and the anticipated timeline for receipt of these key products.
5. To what degree will all of the staffing and reorganization be completed by the implementation date of July 1, 2007?

## **2. Senate Bill 1555 (Speier), Statutes of 2006—Birth Defects Monitoring & TBL**

**Issue:** The budget proposes an increase of \$4.6 million in state support (\$4.2 million in Birth Defects Monitoring Fund, and \$475,000 in Genetic Disease Testing Fund) to **(1) add six new positions across two programs, and (2) provide \$4 million in contract funds to implement Senate Bill 1555 (Speier), Statutes of 2006. Trailer bill legislation to establish a special fund is also being proposed.**

(The program funding piece of this legislation is discussed under Agenda, item #3, below.)

**Specifically, SB 1555, Statutes of 2006 does the following:**

- **Expands the Prenatal Screening Program by adding Inhibin screening (i.e., the fourth marker) to the program and by providing for first trimester screening.** The fee for this program was increased by \$40 for this purpose. This expansion of the program would increase the detection for neural tube defects, Down Syndrome, Trisomy 18 and Smith Lemli Optiz Syndrome to about 90 to 95 percent accuracy;
- **Directs the California Birth Defects Monitoring Program to store and share pregnancy blood samples for the purpose of conducting research about causes, treatments, prevention strategies and screening tests for children's and women's diseases.** The fee for the Prenatal Screening Program was increased by \$10 for this purpose; and
- **Requires the department to educate the public about the benefits of umbilical cord blood banking.** The legislation specifies that these efforts are to be funded using private donations.

**With respect to the expansion of the Prenatal Screening Program, the department is proposing expenditures of \$475,000 (Genetic Disease Testing Fund) to fund four positions including two Research Scientist II positions, a Nurse Consultant II position, and a Senior Information Systems Analyst.**

The Research Scientist II positions will be used to: **(1)** develop and evaluate the clinical chemistry methodology for testing for maternal serum specimens; **(2)** develop First Trimester protocol; **(3)** perform onsite quality assurance reviews; and **(4)** train and conduct quality control of contract laboratories. Once this initial development is completed, ongoing monitoring and adjustments are necessary to maintain the program at optimum level.

The Nurse Consultant position will **(1)** develop coordinator protocols related to addition of Inhibin and First Trimester Screening; **(2)** train coordinator staff on case follow-up protocols; and **(3)** direct coordinators on resolution of complex cases.

The Senior Information Systems Analyst will **(1)** provide database application architecture evaluations and review; **(2)** perform production operations including troubleshooting; and **(3)** provide assistance on database servers and websites. In addition, \$33,000 in contract funds are being requested to conduct ongoing application and database code reviews to ensure adherence to departmental information security policies. These activities are

needed to complete the incorporation of the two expansions of the Prenatal Screening Program into the existing Screening Information System used for the program.

**With respect to the expansion of the California Birth Defects Monitoring Program (CBMP), the department is requesting an increase of \$4.2 million (CA Birth Defects Monitoring Fund). These funds would be allocated as follows:**

- \$3.9 million (CA Birth Defects Monitoring Fund) to contract with the March of Dimes regarding the oversight of the storage of blood samples, development and oversight of the sample retrieval protocol and coordination and racking of the use of the samples by researchers;
- \$320,000 (CA Birth Defects Monitoring Fund) to support two positions including a Research Scientist IV and an Associate Governmental Program Analyst (AGPA). The Research Scientist IV position would (1) oversee peer review process to prioritize access to pregnancy blood samples; (2) write project plans and monitor contractor's work for complex research studies involving health data linkage and pregnancy blood samples; (3) collaborate with the scientific community; and (4) prepare presentations to public health experts regarding findings.

**The Administration also proposes trailer bill legislation to establish a separate special fund—the Birth Defects Monitoring Fund.** The \$10 fee and any interest revenues will be deposited into this special fund for appropriation by the Legislature. A separate special fund will allow for additional administrative oversight.

**Background—Prenatal Screening Program.** The Prenatal Screening Program provides screening of pregnant women who consent to screening for serious birth defects. The program provides public education, and laboratory and diagnostic clinical services through contracts with private vendors meeting state standards. Authorized follow-up services are also provided as part of the fee payment. The fee paid for this screening is **\$162 dollars**. Fees are deposited into the Genetic Disease Testing Fund for support of the program. Where applicable, this fee is paid by the family's insurance, the Medi-Cal Program, or out-of-pocket.

Among other things, SB 1555, Statutes of 2006, expands this program to add Inhibin screening (i.e., the fourth marker) and by providing for first trimester screening.

**Background—California Birth Defects Monitoring Program.** This program began in 1982 and operates as a repository for surveillance data and facilitates scientific research. The department is under contract with the March of Dimes to jointly administer the program

For example, many years ago the program found that folic acid taken at the time of conception prevents several types of birth defects. This finding, in conjunction with other institution's research, was the basis for the federal Food and Drug Administration's decision to fortify grains with folic acid. Recently, the program found that tobacco smoking during pregnancy is associated with development of cleft lip and palate.

The CBDM Program started a sample blood bank in 2003. These samples had been acquired through the Genetic Disease Testing Program (i.e., newborns routinely have a few drops of blood taken from their heels and blotted onto filter paper to test for metabolic diseases). Several studies regarding genetic variants have already been conducted. Among other things, SB 1555, Statutes of 2006, is intended to expand these efforts.

**Subcommittee Staff Recommendation:** The expansion of the Prenatal Screening Program to include Inhibin (i.e., fourth marker) and First Trimester screening as directed by SB 1555, Statutes of 2006, are significant. The department anticipates that the Inhibin screen can be added to the program by September 2007. However the First Trimester screening will not be operational until at least January 1, 2009. Resources are needed in order for this to be a successful implementation. **Therefore, it is recommended to approve the proposal as budgeted.**

**Questions:** The Subcommittee has requested the department to respond to the following questions:

1. Please provide a brief summary of the budget request for this proposal and how it addresses the purposes of SB 1555, Statutes of 2006.

### **3. Genetic Disease Testing Program—The Prenatal Program & Newborn Program**

**Issue:** The budget proposes **total expenditures of \$118.9 million (Genetic Disease Testing Fund) in local assistance for the Genetic Disease Testing Program. This reflects an increase of \$20.7 million (Genetic Disease Testing Fund) as compared to the current year. This program is fully fee supported.**

The proposed expenditures and the proposed increases are shown in the chart below:

<b>Category of Program</b>	<b>Total Proposed for 2007-08</b>	<b>Increase Over Current Year</b>
Newborn Screening	\$45.9 million	\$1.1 million
Prenatal Screening	\$47.6 million	\$15.8 million
Administration—both	\$25.4 million	\$3.8 million
<b>Total Program</b>	<b>\$118.9 million</b>	<b>\$20.7 million</b>

**The \$1.1 million (Genetic Disease Testing Fund) increase in the Newborn Screening Program reflects the first full year of testing for Cystic Fibrosis and Biotinidase Deficiency.** Testing for Cystic Fibrosis and Biotinidase Deficiency were included in the program as directed through Chapter 48, Statutes of 2006 (the Omnibus Health Trailer bill). As allowed by statute, the Director of the Department of Health Services increased fees by \$17.75 on August 1, 2006 to support this expansion in Newborn Screening.

**The Prenatal Screening Program reflects an increase of \$15.8 million.** This increase is for the program to comply with the statutory requirements of Senate Bill 1555 (Speier), Statutes of 2006, as discussed under Agenda Item #2, above. **The proposed increase consists of the following adjustments as shown in the chart below.**

<b>Component of Prenatal Screening</b>	<b>Total Proposed for 2007-08</b>	<b>Increase Over Current Year</b>
Contract Laboratories	\$3.8 million	\$1 million
Technologic Support and Science	\$9.9 million	\$4.7 million
Systems Development, Equipment & Training	\$11.7 million	\$8.5 million
Follow Up Costs	\$4.5 million	\$471,000
Prenatal Diagnostic Centers	\$16.3 million	\$1.1 million
Result Reporting & Fee Collection	\$1.4 million	no change
<b>TOTAL Prenatal Screening Program</b>	<b>\$47.6 million</b>	<b>\$15.8 million</b>

According to the Administration, \$8.5 million of the \$15.8 million total increase is for system development in order to make the necessary changes to implement the changes required under SB 1555—namely the addition of Inhibin and the First Trimester screening. Another key piece of the expenditures is an additional \$4.7 million which is required for reagents to screen for the new conditions. This includes reagents necessary to do development of the

actual screen, quality control, pilot testing and implementation of the expansion statewide. Other expenditures pertain to training, primarily for the end users, and related maintenance of the system as warranted.

**The \$3.8 million (Genetic Disease Testing Fund) increase for Administrative is attributable to salary adjustments, operating expense price increases and adjustments made to the pro rata calculation as directed by the Department of Finance.**

It should also be noted the Genetic Disease Testing Fund received two loans from the General Fund in past years in order to maintain solvency. Specifically, through the Budget Acts of 2003 and 2004, the Genetic Disease Testing Fund received a General Fund loan amount totaling \$10.3 million. **This total loan amount is being repaid to the General Fund in 2007-08.** The revenue Fund Condition Statement for the Genetic Disease Testing Fund reflects action.

**Background—What is the Genetic Disease Testing Program?** The Genetic Disease Testing Program consists of two programs—the Newborn Screening Program and the Prenatal Screening Program. Both screening programs provide public education, and laboratory and diagnostic clinical services through contracts with private vendors meeting state standards. Authorized follow-up services are also provided as part of the fee payment. The programs are self-supporting on fees collected from screening participants through the hospital of birth, third party payers or private parties using a special fund—Genetic Disease Testing Fund.

The Newborn Screening Program provides screening of *all* newborns in California for genetic and congenital disorders that are preventable or remediable by early intervention. The fee paid for this screening is \$103 dollars. Where applicable, this fee is paid by the family's insurance, the Medi-Cal Program, or out-of-pocket.

The Prenatal Screening Program provides screening of pregnant women who consent to screening for serious birth defects. The fee paid for this screening is \$162 dollars. Where applicable, this fee is paid by the family's insurance, the Medi-Cal Program, or out-of-pocket.

**Subcommittee Staff Recommendation:** It is recommended to approve the budget as proposed. It is consistent with the implementation of SB 1555.

**Questions:** The Subcommittee has requested the department to respond to the following questions:

1. Please provide a **brief summary** of the **key** adjustments being requested for **each** program component of the overall Genetic Disease Testing Program.
2. Please clarify the fee structure and the need to make adjustments for overhead expenditures and related costs.

#### **4. Oral Health Assessment as Proposed in Assembly Bill 1433, Statutes of 2006**

**Issue:** The budget proposes an increase of \$221,000 (General Fund) to fund two three-year limited-term positions—a Research Specialist II and a Health Program Specialist—to (1) conduct an evaluation of AB 1433 (Emmerson), Statutes of 2006; and (2) provide a report to the Legislature by January 1, 2010 regarding the effect on children’s oral health as a result of the legislation.

As discussed in more detail below, AB 1433 requires children enrolled in a public kindergarten or first grade to have an oral health assessment. Funds were provided in the Budget Act of 2006 for the local assistance support for implementation of this proposal.

The department is seeking funds and staff for a report contained within the legislation. Specifically, legislation requires the department to conduct an evaluation and submit a report to the Legislature by January 1, 2010. **The legislation also states that: “The Office of Oral Health may receive private funds and contract with the University of California to fulfill the duties described in this subdivision”.**

**Background:** AB 1433 (Emmerson), Statutes of 2006, requires a pupil, while enrolled in kindergarten or first grade (under certain circumstances) in a public school, to present proof of having received an oral health assessment by no later than May 31 of the school year. It also requires all public schools to annually send a report to the local health officer detailing the number of pupils who are subject to this requirement, the number of pupils who received the assessment, and the number of pupils who did not receive the assessment. Local education agencies received funding through the Budget Act of 2006 for this purpose.

With respect to the oral health assessment, eligible children can receive their assessment through the Medi-Cal Program, Healthy Families Program, and certain community clinic programs. Funding for these purposes is provided in these programs.

No funding was provided for the evaluation or reporting requirement due to the language contained in the legislation, as noted above.

**Legislative Analyst’s Office Recommendation—Deny Proposal:** The LAO recommends deleting the \$221,000 (General Fund) and request for two positions for reporting purposes since the enabling legislation provides that the department may receive private funds and contract with the University of California for this purpose.

**Subcommittee Staff Recommendation:** The Subcommittee staff concurs with the LAO’s recommendation. Other means can be explored to conduct the evaluation and provide the report.

**Questions:** The Subcommittee has requested the department to respond to the following questions.

1. DPH, Please provide a brief overview of the budget proposal.

## **5. California Electronic Death Registration System (CA-EDRS)**

**Issue:** The budget proposes an increase of \$1 million (Health Statistics Fund) to support 13 positions (two-year limited-term, until June 30, 2008) and related operating expenses, including a FAX server, to address workload associated with the CA Electronic Death Registration System (CA-EDRS).

**Presently, no department staff has been specifically assigned to this project.** To-date, all work has been done by contractors, including UC Davis, and by existing department staff assigned to other duties (i.e., absorbed any workload previously).

**The department contends that state staff is needed as the CA-EDRS is phased-in across the state.** Department staff is needed for oversight and management of the system to ensure uniform compliance of death registration and timely registration, preservation and dissemination of death records to the public.

**The requested positions, all two-year limited-term, include the following:**

- Staff Services Manager I
- Associate Information Systems Analysts—two positions
- Associate Programmer Analyst
- Staff Services Analyst—three positions
- Key Data Operators—five positions
- Office Technician

**These positions are to be used to do the following key functions:** (1) work with counties and Local Vital Statistic Registrars on CA-EDRS implementation into their existing systems; (2) provide training to various stakeholder groups including to Local Vital Statistic Registrars, coroners, physicians and funeral homes; (3) prepare reports on system concerns and potential enhancements; (4) develop specifications and conduct data export for various systems and for reporting purposes, and (5) key death certificate information into CA-EDRS.

According to the department, as of February 1, 2007, twenty-four of the sixty-one Local Vital Statistic Registrars were using CA-EDRS, or about 44 percent of all California's deaths. If implementation goes as scheduled, thirty Local Vital Statistic Registrars will be using CA-EDRS and will comprise 58 percent of all California deaths by May 1, 2007. The last remaining areas would be Los Angeles, Long Beach and Pasadena which are to be implemented by October 1, 2007.

**CA-EDRS is funded through fees—originally at \$6 per death certificate and now it is at \$4 per certificate (as of January 2005)—that are deposited into the Health Statistics Fund.** According to the fund condition statement for the Health Statistics Fund, there is a projected reserve for economic uncertainty of \$5.1 million (Health Statistics Fund) for 2007-08, even after accounting for this proposed appropriation.

**Background—How CA-EDRS was Initiated:** AB 2550, Statutes of 2002, requires the development and operation of an automated death registration process throughout the state. **The legislation was part of a package of bills to improve vital records administration and to combat identify theft and fraud.** In addition, the legislation provided a funding source through certain fee payments (disposition of human remains).

**A Feasibility Study Report and initial financing were subsequently provided in 2003. This action provided expenditure authority to design, develop, maintain and operate the CA-EDRS.** The department contracted with UC Davis to develop and maintain the system. No new positions were provided for the program, and contract staff has been used to complete most of the work.

**Primarily the system was designed to provide the ability to:**

- Create, process, and register electronic death certificates across all 61 Local Vital Statistic Registrars (i.e., mainly operated by counties)
- Validate the death certificate data before it is submitted for registration
- Create, submit and register amendments
- Track the completion and registration status of a death certificate record
- Export data from CA-EDRS for reporting purposes

The CA-EDRS also facilitates the accuracy and timeliness of registration of a death certificate, which allows the state to better serve the public. The death certificate information will be available to the public within eight working days after the date of death.

According to the DHS, the CA-EDRS has been constructed to meet nationwide standards with functionality to support more efficient interaction with the Social Security Administration and the National Center for Health Statistics.

**Background—Role of Department in Vital Statistics:** The Department of Public Health is responsible for administering and maintaining California's vital records (birth, death and marriage records) in perpetuity. Presently, the department maintains about 45 million records. About 250,000 new death records and 45,000 death amendments are registered each year. Annually, more than 1.5 million certified copies of death certificates are issued in California.

**Subcommittee Staff Recommendation:** It is recommended to approve the proposal as budgeted. No issues have been raised.

**Questions:** The Subcommittee has requested the department to respond to the following questions.

1. Please provide a brief summary of the recent implementation of CA-EDRS and why the positions are being requested.

## **6. Drug Manufacturer, Medical Device Manufacturer, & Home Medical Retailer**

**Issue:** The budget proposes an increase of \$885,000 (Drug and Device Safety Fund) to fund 8 Senior Food and Drug Investigator positions to perform licensing inspections for (1) new California drug and medical device manufacturers, (2) home medical device retailer facilities, and (3) home medical device retailer exemptees.

The department contends that the number of new license applicants has increased significantly since 2003, resulting in a five percent growth of new license applicants submitted annually. As such, the department states it does not have enough staff to conduct licensing inspections for 819 new drug manufacturer, medical device manufacturer, home medical device retailer facility, and home medical exemptee license applicants.

**Background—Overall Program and Fees Paid:** These programs provide consumer protection from unsafe, contaminated, mislabeled, and fraudulent drugs (blood pressure medications, injectable drugs, antibiotics). New drug and medical device manufacturers are required to be inspected and licensed by the DHS prior to distributing products. In addition, AB 1496 (Olberg), Statutes of 2000, requires biennial inspections of existing licensed drug and medical device manufacturers.

New license inspections require comprehensive review of manufacturing facilities, procedures, personnel, and product labeling and advertising before issuance of the manufacturing license.

**All licensing fees from drug and medical device manufacturers and all enforcement fines and penalties are deposited in the Drug and Device Safety Fund.** The current licensing fees assess to drug and medical device manufacturers, and home medical device retailer, and home medical device trailer exemptee licensees are as follows:

<b>License Type</b>	<b>July 2006 Fees</b>
Drug & Medical Device New License	\$1,600
Drug & Medical Device Renewal License	\$1,300
Drug & Medical Device Special or Small	\$850
Prescription Drug Marketing Act	\$100
Home Medical Device Retailer	\$850
Home Medical Device Warehouse	\$425
Home Medical Device Retailer Exemptee-- New	\$100
Home Medical Device Retailer Exemptee-- Renewal	\$150
Out of State Home Medical Device Retailer Facilities	\$150

According to the DHS, fees have not been increased since 2005.

**Background--Role of the U.S. Food and Drug Administration.** It should also be noted that the U.S. Food and Drug Administration (FDA) requires drug and medical device manufacturers to register, but the DHS contends that the federal FDA may not inspect the firm for two or more years after they have registered and initiated manufacturing. Therefore the federal FDA has partnered with the DHS to share inspection information. It is assumed

that the federal FDA will conduct 318 inspections on a biennial basis. (The DHS says that they have taken this relationship into consideration in calculating their workload level.)

**Subcommittee Staff Recommendation:** It is recommended to approve the positions as proposed.

**Questions:** The Subcommittee has requested the department to respond to the following questions.

1. Please describe the role of the department in conducting these inspections.
2. Please provide a brief summary of the budget proposal and how the need for the requested 8 positions was calculated.

## **7. Assembly Bill 1382 (Nakanishi), Statutes of 2006—Prescription Lens**

**Issue:** The budget proposes an increase of \$131,000 (General Fund) to support a Senior Food and Drug Investigator and related operating expenses to implement AB 1382, Statutes of 2006.

The investigator position would be used to (1) respond to complaints; (2) conduct investigations to determine non-compliance and associated enforcement activities; (3) prepare samples and laboratory analysis requests; and (4) serve as a witness in prosecutions.

Specifically, AB 1382 requires the department to (1) regulate misbranded and adulterated prescription lenses and contact lenses sold by unlicensed individuals; and (2) take action against unlicensed individuals engaged in deceptive marketing practices relating to contact lenses, including plano (decorative) contact lenses.

The department's overall enforcement authority includes embargo of volatile medical devices, voluntary condemnation and destruction, administrative fines, or criminal or civil actions.

**Background:** The purpose of the legislation was to address the problem of non-corrective, plano (decorative) contact lenses being distributed directly to consumers without a prescription by unlicensed individuals, without proper sanitizing, and without proper fitting by an eye care professional. Some of these contact lens products are imported or sold outside the normal streams of commerce (such as flea markets) and thus are not covered in existing law.

AB 1382, Statutes of 2006, delegates the department, the California Board of Optometry, and the Medical Board of California the authority to enforce the provisions of this legislation against any person illegally selling contact lenses.

**Questions:** The Subcommittee has requested the department to respond to the following questions.

1. Please describe the role of the department in conducting this work in other unlicensed areas. Why could this work not be done at the local level where applicable?
2. Please provide a brief description of how the work would be accomplished by the department and how enforcement would occur.